UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

15/AUG/2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 70506-GNL

Name of Pesticide Product:	Bifenture 17
EPA Reg. No.:	70506-GNL
DP Barcode:	D411317
Decision No.:	477113
Action Code:	R310
PC Code:	128825 (bifenthrin)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew 8/15/13
T.L. Toxicologist

To: BeWanda Alexander, RM Team 10
Insecticide Branch
Registration Division (7505P)

Applicant: United Phosphorus, Inc.
630 Freedom Business Center, suite 402
King of Prussia, PA 19406

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Bifenthrin	17.15
Other Ingredient(s):	82.85
Total:	100.00%

ACTION REQUESTED: The Risk Manager requests a review of six acute toxicity studies submitted to support the registration of EPA File Symbol 70506-GNL.

BACKGROUND: United Phosphorus, Inc. has submitted six acute toxicity studies with MRIDs 490938-04 to -09 to support the registration of Bifenture 17, EPA File Symbol 70506-GNL. The The TRB Product Chemistry Team reviewed and accepted the basic CSF submitted for 70506-GNL (Abramovitch; D411316; EPA File Symbol 70506-GNL; 15/AUG/2013).

GLP: Yes

DEVIATIONS: None

LABELING:

PRODUCT ID #: 070506-00305

PRODUCT NAME: Bifenture 17 Insecticide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. [Wear protective eyewear.]* Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

*[Protective eyewear may be specified, if appropriate.]

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Product Reg. No.: 70506-GNL
Product Name: Bifenture 17

1. DP BARCODE: 411317				
2. PC CODE: 128825				
3. CURRENT DATE: 15/AUG/20132013				
4. TEST MATERIAL: KFD-110-03 (Batch # 507-67A; EPSL Ref. No. 121012-2H; 16.57% Bifenthrin; pH 8.6 (as 1% dispersion in water); density 1.027 g/mL; white to off-white suspension concentrate; administered as received)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat Eurofins PSL Study #35433/February 18, 2013 OCSPP 870.1100; OECD 425	49093804	LD_{50} Females = 550 mg/kg (95% PL CI of 265.4 to 1520 mg/kg) 10 animals tested at 175, 550 or 2000 mg/kg mortality: 550 mg/kg: 2/4 died within 1 day of test substance administration; 2000 mg/kg: 3/3 died within 1 day of test substance administration 175 mg/kg (3 animals): clinical signs: none; body weight gains; no gross abnormalities at necropsy 550 mg/kg (4 animals): 2/4 died; clinical signs prior to death: tremors; clinical signs in survivors: reduced fecal volume and tremors with recovery by day 4; gross necropsy of decedents revealed discoloration of the lungs or intestines, stomach, liver and/or spleen and/or a mottled liver. 2000 mg/kg (3 animals): 3/3 died; clinical signs noted prior to death: tremors, irregular respiration, nasal discharge, and/or hypoactivity; gross necropsy revealed discoloration of the lungs and/or mottled liver.	III	A

Acute dermal toxicity / rat Eurofins PSL Study #35434/February 5, 2013 OCSPP 870.1200; OECD 402	49093805	LD_{50} > 5000 mg/kg (both sexes) mortality: 1 female died within 1 day of test substance application; no toxic signs noted before death; clinical signs: ano-genital staining at 5 dose sites on days 1 and 2; dermal irritation: erythema at 7/10 dose sites from days 1-3, desquamation at all dose sites between days 2-10; 4 survivors lost weight by day 7 but all survivors gained weight by day 14; gross necropsy revealed extremely red lungs and slightly distended and yellowish intestines.in decdedent only	IV	A
Acute inhalation toxicity / rat Eurofins PSL Study #35435/February 18, 2013 OCSPP 870.1300; OECD 403	49093806	LC_{50} > 5.06 mg/L (both sexes) two levels tested: 2.13 mg/L (5 females) and 5.06 mg/L (5 males and 5 females) 2.13 mg/L: MMAD: 3.31, 2.74 µm GSD: 2.58, 2.56 5.06 mg/L: MMAD: 3.19, 3.20 µm GSD: 2.47, 2.39 mortality: 5.06 mg/L: 2/5 females died on day 1; 2.13 mg/L: 1/5 females died on day 1; 2.13 mg/L: clinical signs: irregular respiration, red facial staining, ano-genital staining, twitching, red nasal discharge, red ocular discharge with recovery by day 8; toxic signs in decedent: irregular respiration and twitching; all surviving animals lost weight between days 1 and/or 3, all showed weight gain thereafter through day 14; all surviving animals lost weight between days 1 and/or 3, all showed weight gain	IV	A

		thereafter through day 14; necropsy findings in decedent only: mottled liver and moderately distended, yellow intestines and stomach 5.06 mg/L: clinical signs: sensitivity to sound, hypoactivity, irregular respiration, ano-genital staining, twitching, red nasal discharge, red facial staining, abnormal gait, tremors, hunched posture, red ocular discharge, with recovery by day 9; toxic signs in decedents: hypersensitivity to sound, hypoactivity, irregular respiration, twitching, red nasal discharge, abnormal gait; hunched posture, tremors necropsy findings in decedent only: areas of dark discoloration in liver, extremely distended, red stomach, extremely distended intestines		
Primary eye irritation / rabbit Eurofins PSL Study #35436/February 5, 2013 OCSPP 870.2400; OECD 405	49093807	3 males tested ocular anesthetic used no corneal opacity; iritis in one eye at 1 hr only; positive conjunctivitis (score of 2-3 for redness, chemosis and/or discharge) in 3/3 eyes at 1 and 24 hrs; score of 1 for redness in 2/3 eyes through day 4; no positive scores at 48 hrs and all eyes clear by day 7	III	A

Primary dermal irritation / rabbit Eurofins PSL Study #35437/February 5, 2013 OCSPP 870.2500; OECD 404	49093808	PDI = 0.0 3 males tested no irritation observed	IV	A
Dermal sensitization /mouse (LLNA) Eurofins PSL Study #35438/February 26, 2013 OCSPP 870.2600; OECD 429	49093809	Is *not* a sensitizer appropriate positive control provided	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap